DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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DEC 10 2002

Ms. Paula Turner
Label Specialist
Young Living Essential Oils
250 South Main Street
Payson, Utah 84651

Dear Ms. Turner:

This is in response to your letter of November 12, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Young Living Essential Oils is making the following claim for its product **Super B**:

> "May reduce the risk of vascular disease as part of a well-balanced diet that is low in saturated fat and cholesterol, folic acid, vitamin B6 and B12."

This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA evaluated the above claim in response to the court decision directing the FDA to consider qualified health claims for dietary supplement labeling (*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999))[1]. FDA found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.

FDA announced on May 15, 2001 that it intended to exercise enforcement discretion to permit dietary supplement labels and labeling to bear a qualified health claim about the relationship between B vitamins and vascular disease; this announcement identified the claim that the agency intended to exercise enforcement discretion to permit a firm to use in its dietary supplement labeling. The announcement also identified a disclaimer that must be immediately adjacent to and directly beneath the claim with no intervening material that separates the claim from the disclaimer. A copy of this announcement can be found on FDA's web site at: http://www.cfsan.fda.gov/~dms/ds-labl.html.

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This kind of health claim is for dietary supplements only and came about as a result of the U.S. Court of Appeals for the D.C. Circuit 1999 decision in the case of Pearson v. Shalala [64 F.3d 650 (D.C. Cir. 1999)]. A detailed discussion of this matter can be found in the agency's Federal Register notice of December 1, 1999, 64 FR 67289, (http://www.cfsan.fda.gov/~lrd/fr991201.html). In the October 6, 2000 Federal Register notice, FDA published its updated strategy for implementation of the court decision. It can be found on the Web at: http://www.cfsan.fda.gov/~lrd/fr001006.html

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A dietary supplement bearing a claim that is not properly qualified or consistent with the weight of the evidence is subject to regulatory action as a misbranded food under 21 U.S.C. 343(r)(1)(B), a misbranded drug under 21 U.S.C. 352(f)(1), and as an unapproved new drug under 21 U.S.C. 355(a).

However, the claim cited in your letter does not appear to be a claim made in accordance with the conditions set forth in the May 15, 2001 announcement. Your claim states "May reduce the risk of vascular disease as part of a well-balanced diet that is low in saturated fat and cholesterol, folic acid, vitamin B6 and B12." This claim conveys the message that your product is intended to reduce the risk of vascular disease in diets that are low in folic acid, vitamin B6, and B12, rather than the fact that it is the folic acid, vitamin B6, and B12 in your product, when used as part of a well-balanced diet that is low in saturated fat and cholesterol (emphasis added), that is intended to be beneficial. We suggest that you consider revising your claim after reviewing the model claims contained in the reference documents cited above.

Please contact us if you require further assistance.

Sincerely yours,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Denver District Compliance, HFR-SW240

November 12, 2002

Young Living ESSENTIAL OILS™

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. Street S.W.
Washington, D.C. 20204

Re: Notification for Statements on Dietary Supplement Labeling

Dear Sir/Madam:

This notification is being submitted on behalf of Young Living Essential Oils, Payson, Utah, a distributor of dietary supplement products (hereafter "Young Living").

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343 (r) (6), and in accordance with the authorized provisions of 21 CFR § 101.93 (a), your Agency is hereby notified that Young Living proposes to make and/or has made statements of "nutritional support", as described in 21 U.S.C. § 343 (r) (6) (A), for its dietary supplements as follows:

Product Name	Statement(s)
Super B	May reduce the risk of vascular disease as part of a well-balanced diet that is low in saturated fat and cholesterol, folic acid, vitamin B6 and B12. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.

This information can be located in the Settlement Reached for Health Claim Relating B Vitamins and Vascular Disease issued on May 15, 2001.

The undersigned certifies on behalf of Young Living Essential Oils that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,

Paula Turner

Paula Turner, Label Specialist

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